

# Mercy Wellness Center

Mercy Medical Center

August 4, 1999

FDA/CDRH Office of Compliance  
Division of Enforcement III  
Attention: Stewart Crumpler  
2098 Gaither Road  
Rockville, MD 20850

Re: **Exemption/Variance request for Performance Standard for Electrode Lead Wires and Patient Cables**

Dear Mr. Crumpler:

Thank you **for** responding to my letter **from** March 18, 1999. Your **information** was very helpful.

As stated in my previous letter, our efforts to find "inexpensive adapters" or "retrofit" our existing **physical therapy equipment** to comply with safety **standards for lead wires and patient cables** have been **unsuccessful**. Complicating **our** situation is **the number of rural satellite locations** in our region **that** we provide services. Each **facility** maintains a minimum of equipment, yet, replacement would involve a large **expense**.

We are requesting an exemption or variance **from the** Performance Standard for Electrode Lead Wires and Patient Cables, **specifically for the** physical therapy equipment **at the** following facilities:

Mercy Wellness Center  
512 Main Street  
Williston, ND 58801

Mercy Medical Center  
Physical Therapy Department  
1301 15<sup>th</sup> Avenue West  
Williston, ND 58801

McKenzie County Memorial Hospital  
Physical Therapy Department  
508 North Main Street - PO Box 548  
Watford City, North Dakota 58854

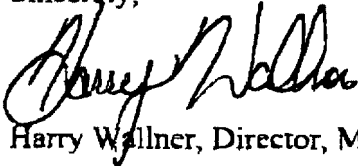
Tioga Medical Center  
Physical Therapy Department  
810 North Welo Street  
PO Box 159  
Tioga, ND 58852-0159

Roosevelt Memorial Medical Center and Nursing Home  
Physical Therapy Department  
818 Second Avenue East  
Culbertson, MT 59218

Indian Health Service  
Physical Therapy Department  
Box 69  
Poplar, MT 59218

You will find **enclosures listing** the equipment we would need to replace in each **department as** well as my original letter to your office. If I can be of any additional assistance, please feel **free** to contact me. Thank you for earliest consideration of our petition.

Sincerely,

A handwritten signature in black ink, appearing to read "Harry Wallner", written over the printed name.

Harry Wallner, Director, Mercy Wellness Center

**Mercy Wellness Center Physical Therapy - Williston, ND****Microcurrent Electric Stimulator - 1 unit**

Manufacturer: Monad Corporation  
 Model, **MENS 5000i**  
 Serial Number, SK0109

**Ultrasound/Electric Stimulator Combination - 3 units**

Manufacturer: Chattanooga **Corp**  
 Model: **Intelect** Model 700  
 Serial **Numbers**: 3362 / 4098 / 2343

**Ultrasound - 1 unit**

Manufacturer, EXCEL Tech. Ltd. - Ultra Max  
 Model: Ultra sx  
 Serial Number: **UMX** 960700 1

**Electric Stimulator - 1 unit**

Manufacturer. **Physio** Technology, Inc.  
 Model. **OmniStim**  
 Serial Number: 2279

**Neuromuscular Electric Stimulator - 1 unit**

Manufacturer **Medtronic**  
 Model. Respond **II** Model 3 128  
 Serial Number: nor available

**Iontophoresor - 1 unit**

Manufacturer. **Empi**  
 Model: **DuPel**  
 Serial Number: 516402

**Neuromuscular Biofeedback - 1 unit**

**Manufacturer** The Prometheus Group  
 Model: Pathway **MR-20**  
 Serial Number: not available

**Mercy Medical Center Physical Therapy - Williston, ND**

**TENS (Transcutaneous electrical stimulators) - 3 units**

Manufacturer: **Empi**  
 Model: **Empix XL**  
 Serial Numbers: 502473 / 885996 / 711795 1

**Iontophoresor - 1 unit**

Manufacturer: **Empi**  
 Model: **Dupel**  
 Serial Number: 5234545

**Iontophoresor - 1 unit**

Manufacturer: **Motion Control**  
 Model: **PM 600**  
 Serial Number: 4740

**Interferential Electric Stimulator - 1 unit**

Manufacturer: **Physio Technology, Inc**  
 Model: **Omnistim 3020**  
 Serial Number: 1612

**Ultrasound - 1 unit**

Manufacturer: **Enraf Nonius Henley International**  
 Model: **Sonopuls 434**  
 Serial Number: 13-085 1

**Ultrasound/Electric Stimulator Combination - 1 unit**

Manufacturer: **Chattanooga Corp.**  
 Model: **Intelect Model 700**  
 Serial Number: 2433

**Ultrasound/Electric Stimulator Combination - 3 units**

Manufacturer: **Chattanooga Corp**  
 Model: **Intelect Model 700C** 73579  
 Serial Numbers: 3583 / 3678 / 2620

**Neuromuscular Electric Stimulator (NMES) - 1 unit**

Manufacturer: **Medtronic**  
 Model: **Respond II Model PM 600**  
 Serial Number: LM00024 19N

**Roosevelt Memorial Hospital - Culbertson, MT**

**Ultrasound/Electric Stimulator Combination - 1 unit**

Manufacturer: **Chattanooga Corp.**  
 Model: **Intelect**  
 Serial Number: **SN2620**

**Tioga Medical Center - Tioga, ND****Ultrasound - 1 unit**

**Manufacturer:** Physio Technology, Inc.  
**Model:** Omnisound **3070C**  
**Serial Number,** 1548

**Electric Stimulator - 1 unit**

**Manufacturer:** Physio Technology, Inc.  
**Model,** **OmniStim** 3020  
**Serial Number.** 1657

**McKenzie County Memorial Hospital - Watford City, ND****Electric Stimulator - 1 unit**

**Manufacturer** Physio Technology, Inc  
**Model:** **OmniStim** 3010  
**Serial Number** 2502

**Ultrasound - 1 unit**

**Manufacturer** EXCEL Ultra Max  
**Model.** Ultra **SX**  
**Serial Number.** **UMX** 9309040

**Electric Stimulator - 1 unit**

**Manufacturer:** **Mettler** Electronics  
**Model :** **SYS STIM** 206 - ME206  
**Serial Number** **17ST2088**

**Neuromuscular Electric Stimulator - 1 unit**

**Manufacturer:** **Medtronic**  
**Model :** **Respond II Model 3** 128  
**Serial Number:** **LM0038713N**

**Indian Health Services - Poplar, MT****Ultrasound/Electric Stimulator Combination - 2 units**

**Manufacturer.** Chattanooga  
**Model:** **Intelect**  
**Serial Numbers:** **SN3557 / SN3567**

**Transcutaneous Electric Neuromuscular Stimulator (TENS) - 6 units**

**Manufacturer:** not available  
**Model:** Neutralizer **II**  
**Serial Numbers:** **403142 / 403146 / 402521 / 402538 / 403148 / 564032**

March 18,1999

Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Devices and Radiologic Health (HFZ-343)  
Office of Compliance  
Attention: Stewart Crumpler  
5600 Fishers Lane  
Rockville, Maryland 20857

Re: Compliance with the Performance Standard for Electrode Lead Wires and Patient Cables

Dear Mr. Crumpler:

I am writing to you to let you know that our efforts to comply with the safety standards for lead wires and patient cables have been unsuccessful as well as time consuming. We are requesting direction from your office in finding assistance with becoming compliant and/or a variance or exemption from the FDA.

Representing our Risk Management Committee at Mercy Medical Center, Mark Wassink (Director of Physical Therapy) and I have made several attempts since October 1998 to find "inexpensive adapters" or a way to "retrofit" our physical therapy equipment. Between our two departments as well as the satellite clinics we serve in our region we have well over thirty pieces of equipment to replace if we are not able to adapt existing equipment. We have phoned our major distributors as well as written to the Customer Services/Technical Support departments of six manufacturers without any kind of assistance. Our BioMedical Engineering Department has also made these same kinds of efforts, without any success. A concern of ours is that the companies would rather sell us new equipment than assist us.

We fully understand our need to be compliant with the new standards but will suffer a considerable hardship if we are required to replace all of our equipment.

Your earliest assistance would be appreciated.

Sincerely,

Harry Wallner, Director

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CATHOLIC HEALTH  
INITIATIVES

# Mercy Wellness Center

Mercy Medical Center

September 21, 1999

Jennie C. Butler, Chief  
Dockets Management Branch  
FDA/CDRH Office of Compliance  
Division of Enforcement III  
2098 Gaither Road  
Rockville, MD 20850

Dear Ms. Butler:

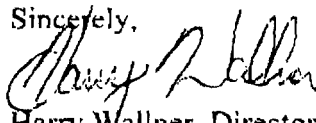
Thank you for alerting me to the two omissions in my August 4, 1999 request for variance from performance standards for electrode lead wires and patient cables.

Regarding 10.30 C Environmental Impact: Categorical excluded physical therapy equipment in the service area of Mercy Medical Center will have a positive impact on the environment by keeping the existing equipment in use and out of the local landfills.

Accompanying this fax is the signed certification.

Thank you for your assistance in this matter.

Sincerely,



Harry Wallner, Director  
Mercy Wellness Center

09/21/89 TUE 10:42 FAX 3019278870

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DMSP:DMB

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## § 10.30

## C. Environmental Impact

(A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.)

## D. Economic Impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition. A statement of the effect of requested action on: (1) cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

## E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) *David H. Jones*  
(Name of petitioner) *David H. Jones*  
(Mailing address) *1011 1st St*  
(Telephone number) *(704) 574-1848*

(c) A petition which appears to meet the requirements of paragraph (b) of this section and § 10.20 will be filed by the Dockets Management Branch, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Dockets Management Branch for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. Related petitions may be filed together and given the same docket number. The Dockets Management Branch will promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) An interested person may submit written comments to the Dockets Management Branch on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

(e)(1) The Commissioner shall, in accordance with paragraph (c)(2), rule

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upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.

(2) Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a FEDERAL REGISTER notice) implementing the approval;

(ii) Deny the petition; or

(iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. The petitioner is to be notified in writing of the Commissioner's decision. The decision will be placed in the public docket file in the office of the Dockets Management Branch and may also be in the form of a notice published in the FEDERAL REGISTER.

(4) The Commissioner shall furnish a response to each petitioner within 90 days of receipt of a petition filed under section 505(j)(2)(C) of the act. The response will either approve or disapprove the petition. Agency action on a petition shall be governed by § 314.62 of this chapter.

(f) If a petition filed under paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, § 10.40 or § 10.50 also apply.

(g) A petitioner may supplement, amend, or withdraw a petition in writing without agency approval and without prejudice to resubmission at any time until the Commissioner rules on